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## NOTICE OF ALLOWANCE AND FEE(S) DUE

47888 7590 02/09/2012  
 HEDMAN & COSTIGAN, P.C.  
 1230 AVENUE OF THE AMERICAS  
 7th floor  
 NEW YORK, NY 10020

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/09/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,315	04/08/2008	Lawrence Solomon	1322-035	2612

TITLE OF INVENTION: PHARMACEUTICAL TABLETS COMPRISING TWO OR MORE UNITARY SEGMENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$870	\$300	\$0	\$1170	05/09/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



Docket No.: ABT-035

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Lawrence Solomon, et al.

Serial No.: 10/598,315

Group Art Unit: 1615

Filed: April 8, 2008

Examiner: Sasan, A.

**For: SCORED PHARMACEUTICAL TABLETS COMPRISING A PLURALITY  
OF SEGMENTS**

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**COMMENTS ON REASONS FOR ALLOWANCE**

Sir:

This is in response to the Reasons for Allowance and Examiner's Amendment (copies attached) issued in the subject application. The Examiner's Amendments to claims 43-45 and 50 are accurate and accepted; however, the Examiner's Amendments to claims 48 and 49 are incorrect. The Examiner's Amendments should reflect that term "first" segment is substituted with the term "top inactive non-unitary" segment, as agreed in the telephonic interview conducted 18 January 2012 (see Examiner-Initiated Interview Summary issued with the Notice of Allowance, copies attached).

Specifically, claims 48 and 49 should be correctly amended as follows:

Claim 48 (currently amended). A method of breaking a pharmaceutical tablet as defined in claim 34 wherein said tablet is broken by applying force to said first and said second unitary segments to cause the tablet to break through said first top inactive unitary segment.

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Claim 49 (currently amended). A method of breaking a tablet as in claim 48 that comprises first breaking said tablet through said first top inactive unitary segment to obtain a tablette that contains part of said first top inactive unitary segment plus unitary segments and thereafter breaking said tablet between said first and said second unitary segments so that the tablet breaks substantially completely within said first top inactive unitary segment.

In the Examiner's Amendment provided with the Notice of Allowance, claims 48 and 49 were incorrectly amended. In a telephonic interview conducted 18 January 2012 (see Examiner-Initiated Interview Summary issued with the Notice of Allowance) it was agreed to replace the term "first segment" with the term "top inactive non-unitary segment." However, claim 48 was shown to incorrectly replace the phrase "first and second unitary segments" with the phrase "top inactive non-unitary segment." Applicants respectfully request reconsideration and correction of the Examiner's Amendment consistent with the claim 48 amendment shown above.

Regarding claim 49, the term "first segment" was correctly replaced with the term "top inactive non-unitary segment" in the first instance. However, the term "first segment" is recited three times within that claim. Accordingly, the Examiner's Amendment should reflect the agreed-upon replacement in each instance. Applicants therefore respectfully request reconsideration and correction of the Examiner's Amendment consistent with the claim 49 amendment shown above.

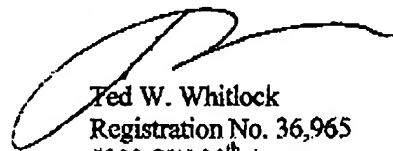
Applicants believe the subject claims 48 and 49, as shown above, are correctly amended and consistent with the amendments agreed to in the telephonic interview conducted 18 January 2012. Applicants respectfully request that the issued claims reflect these corrections.

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Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

Dated: 29 February 2012



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Registration No. 36,965  
5323 SW 38<sup>th</sup> Avenue  
Ft. Lauderdale, Florida 33312  
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Fax: 954-986-2120



<b>Examiner-Initiated Interview Summary</b>		Application No.	Applicant(s)
		10/598,315	SOLOMON ET AL
		Examiner	Art Unit
		ARADHANA SASAN	1615

All participants (applicant, applicant's representative, PTO personnel):

(1) ARADHANA SASAN (3) \_\_\_\_\_

(2) TED WHITLOCK (4) \_\_\_\_\_

Date of Interview: 18 January 2012

Type: ☒ Telephonic ☐ Video Conference  
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.  
 If Yes, brief description: \_\_\_\_\_

Issues Discussed ☐ 101 ☐ 112 ☐ 102 ☐ 103 ☒ Others  
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 43-45 and 48-50

Identification of prior art discussed: \_\_\_\_\_

Substance of Interview  
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

The Examiner contacted Applicant's representative to inform him that after reviewing the amendments, remarks and declaration (filed 01/09/12) the case was in condition for allowance. The Examiner also requested approval for an Examiner's amendment to correct the dependency of claims 43-45 and to replace the phrase "first segment" with "top inactive non-unitary segment" in claims 48-50. Applicant's representative agreed to the corrections by Examiner's amendment.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Aradhana Sasan  
 Examiner, Art Unit 1615

U.S. Patent and Trademark Office

**Notice of Allowability**

Application No.

10/598,315

Applicant(s)

SOLOMON ET AL.

Examiner

ARADHANA SASAN

Art Unit

1615

**- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment, remarks and declaration filed on 01/09/2012
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 34-51.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-848) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(e)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 06/01/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20120118.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_

/Aradhana Sasan/  
Examiner, Art Unit 1615

Application/Control Number: 10/598,315  
Art Unit: 1615

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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ted Whitlock on January 18, 2012.

2. The application has been amended as follows:

- Claims 43-45 should be dependent on claim 34, and not 44.
  - a. Claim 43 (new). A pharmaceutical tablet as defined in claim 44 34 in which said drug is warfarin.
  - b. Claim 44 (new). A pharmaceutical tablet as defined in claim 44 34 in which said drug is digoxin.
  - c. Claim 45 (new). A pharmaceutical tablet as defined in claim 44 34 in which said drug is levothyroxine.
- Claims 48-50 should be amended as follows:
  - d. Claim 48 (new). A method of breaking a pharmaceutical tablet as defined in claim 34 wherein said tablet is broken by applying force to said first and ~~said second unitary segments~~ top inactive non-unitary segment to cause the tablet to break through said first segment.
  - e. Claim 49 (new). A method of breaking a tablet as in claim 48 that comprises first breaking said tablet through said first segment top inactive non-unitary

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teach tamping of an active-containing layer that has a level top surface on which an inactive non-unitary segment is deposited. Hess does not teach breaking the tablet through the top inactive non-unitary segment.

- iii. The declaration under 37 CFR 1.132 by Dr. David P. Beach (filed 01/09/12) has been fully considered and was persuasive. The declarant states that the process of manufacturing the tablets according to Hess is carried out without a tamping step applied to the first layer, and that without tamping the first layer before depositing the second composition, the first layer will not have a uniform (or level) surface to interface with the second composition. The declarant provided a comparison of a bi-layer tablet with an embossed upper (top) punch (FIG. 1) and a bi-layer tablet scored with embossed lower (bottom) punch (FIG. 2 – instant invention) which shows that when an embossed bottom tablet punch is used, a straight-line, planar interface of the layers results, and there is no "push effect" or mingling of the active layer into the inactive layer, or vice versa.
- iv. A further prior art search did not disclose a reference that teaches the specific arrangement of the compressed, layered pharmaceutical tablet as recited in instant claims.

Therefore, the claimed invention is novel and unobvious over the prior art of record.

#### ***Comments***

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably



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Art Unit: 1615

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- iv. A further prior art search did not disclose a reference that teaches the specific arrangement of the compressed, layered pharmaceutical tablet as recited in instant claims.

Therefore, the claimed invention is novel and unobvious over the prior art of record.

#### ***Comments***

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**Conclusion**

5. Claims 34-51 are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner  
Art Unit 1615